K111431

AUG - 1 2011

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7602 - Phone
(714) 516-7472 - Facsimile
Wendy Garman - Contact Person

Date Summary Prepared: May 2011

Device Name:

- Trade Name – *B1P Adhesive*
- Common Name – Bonding Agent
- Classification Name – Resin Tooth Bonding Agent, per 21 CFR § 872.3200
- Product Code: KLE

Devices for Which Substantial Equivalence is Claimed:

- Pentron Clinical, Dentin Conditioning and Adhesive (Bond 1), K973388
- Kerr Corporation, Optibond Solo Plus 2, K991808
- Heraeus Kulzer GmbH, IBond Total Etch, K083652

Device Description:

B1P Adhesive is a fifth generation dental bonding agent that is intended to be used for direct composite bonding and indirect restoration cementation in combination with a dental restorative material. The formula is used based on a total etch technique and combines the primer and adhesive into one component. The application procedure requires steps of acid etching and rinsing, followed by the application of the *B1P Adhesive*. It is a light curable adhesive with the option of being dual cured when mixed with the dual cure activator.

Intended Use of the Device:

B1P Adhesive is an adhesive designed to be used for all direct and indirect applications including, but not limited to, the following:

Direct Applications

- Direct bonding to dentin and/ or enamel
- Bonding composite to composite, porcelain and/ or metal Opaquing metal (used in conjunction with an opaque resin stain or cement)
- Bonding with dual cure and self cure composite resins, such as cements and core build up materials
- Amalgam sealing
- Dentin sealing

Indirect applications

- Indirect bonding of all composite, all ceramic, PFM and alloy crowns, bridges, inlays, onlays and veneers (used in conjunction with resin luting agents)
- Bonding of fiber and metal posts (in conjunction with resin luting agents)

Summary of Technological Characteristics:

B1P Adhesive is substantially equivalent to three other legally marketed devices in the United States: Dentin Conditioning and Adhesive (Bond 1), Optibond Solo Plus 2 and IBond Total Etch.

B1P Adhesive functions in a manner similar to and is intended for the same use as Dentin Conditioning and Adhesive (Bond 1) that is currently marketed by Pentron Clinical. Both products are acetone based and utilize the same adhesive monomer. *B1P Adhesive* differs in that it incorporates glutaraldehyde as a desensitizer, can be stored at ambient temperature, has both a bottle and a single dose configuration, and requires the use of only one coat.

B1P Adhesive functions in a manner similar to and is intended for the same use as Optibond Solo Plus 2 that is currently marketed by Kerr Corporation. Both products can be stored at ambient temperature, are both applied in a single coat, utilize filler technology to increase bond strength, and are both offered in a bottle and a single dose configuration. *B1P Adhesive* differs in that it uses a different adhesive monomer and it contains glutaraldehyde as a desensitizer.

B1P Adhesive functions in a manner similar to and is intended for the same use as IBond Total Etch that is currently marketed by Heraeus Kulzer GmbH. Both products contain glutaraldehyde as a desensitizing agent, require the use of only one coat, bond to both dentin and enamel, employ filler technology to increase bond strength, require the use

of an etching agent and can both be stored at ambient temperature. *B1P Adhesive* differs in that it may be dual cured when mixed with the dual cure activator, and employs different main adhesive components.

Non-Clinical Test Data

Biocompatibility studies have been completed according to ISO 10993, which demonstrates that *B1P Adhesive* is safe for its intended use.

This 510(k) submission also includes data from bench testing used to evaluate the performance characteristics of *B1P Adhesive* compared to the predicate devices. The characteristics evaluated include direct and indirect bonding strengths.

Clinical Testing

Clinical testing has not been conducted on this product.

Conclusion:

Based upon biocompatibility tests, similar technological characteristics to the predicate devices and bench testing, the clinical performance of *B1P Adhesive* is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pentron Clinical
C/O Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

AUG - 1 2011

Re: K111431
Trade/Device Name: B1P Adhesive
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: May 20, 2011
Received: May 23, 2011

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111431

Device Name: *B1P Adhesive*

Indications For Use:

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Direct Applications

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Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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